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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/071,505      | 02/08/2002  | Ingrid Henriksen     | NIDN-10439          | 8899             |

36335 7590 05/22/2006

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| EXAMINER |
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SHARAREH, SHAHNAMEH J

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| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/071,505

Applicant(s)

HENRIKSEN ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,5-9,11-17 and 19 is/are pending in the application.  
4a) Of the above claim(s) 8,9 and 13-17 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1, 3, 5-7, 11-12, 19 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Applicant's reply filed on February 21, 2006 has been entered. Claims 1, 3, 5-9, 11-17, 19 are pending. Claims 8-9, 13-17 stand withdrawn. Claims 1, 3, 5-7, 11-12, 19 are under consideration.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 3, 5-7, 11-12, 19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Unger US Patent 6,033,645 for the reasons of record.

#### ***Response to Arguments***

3. Applicant's arguments with respect to the rejected claims have been considered but are persuasive.

4. Applicant has argued that the contrast agent of Unger is administered over a period of 5 seconds to 50 seconds (Response at page 3, 2<sup>nd</sup> para). As pointed out throughout the prosecution, Unger explicitly disclaims any specific rates to be the exhaustive rate limitation. Unger further elaborates on factors that determine the ultimate rate.

Unger at col 45 states:

The compositions may be administered over a period of time which can vary and depends upon a variety of factors including, for example, the volume of the composition being administered, the age and weight of the patient, the particular materials employed in the compositions, including, for example, lipids, polymers, proteins, vesicles, gases and/or gaseous precursors, the purpose for the administration (for example, diagnostic or therapeutic), the region of interest, the mode of administration, the size of the vesicles (in the case of vesicle compositions), and the like. An exemplary administration time for the compositions described above is about 5 seconds. Dividing the gas dose by this time period provides a gas administration rate which can be expressed as cc gas/Kg-sec. Thus, a gas dose of, for example, about  $1 \times 10^{-4}$  cc gas/Kg and an administration time of 5 sec provides a gas administration rate of about  $2 \times 10^{-5}$  cc gas/Kg-sec.

It is to be understood that the foregoing specific gas concentrations, composition doses, administration times and administration rates are for purposes of illustration only, and not for purposes of limitation.

Accordingly, modifications of the rate of administration would have been well within the purview of one of ordinary skill in the art.

5. Applicant also argues that Unger discloses a different problem than the problem of the current invention and one of ordinary skill in the art would not have been motivated to modify the administration rate and period to reach the present invention (see Remarks at page 3, 3<sup>rd</sup> para).

6. In response Examiner states that the fact that applicant has recognized another advantage, which would, flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

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7. Here, Unger discloses similar method steps as those instantly claimed except the instantly recited duration of infusion. There is no evidence on record or in the art that would discourage one of ordinary skill in the art to modify and optimize duration of infusion to improve the quality of imaging process. Accordingly, Examiner states that the mere fact that there is an alternative means of improving ultrasound imaging, as described by Unger, does not preclude optimization of Unger's infusion rates that would render the instantly recited infusions rate obvious.

8. Generally, "disclosed examples and preferred embodiments do not constitute a teaching which is away from a broader disclosure or nonpreferred embodiments." *In re Susi*, 169 USPQ 423 (CCPA 1971). "In general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the results sought by the applicant." *In re Gurley*, 31 USPQ2d 1130, 1131-2 (Fed. Cir. 1994). Accordingly, consistent with the rulings in *In re Gurley*, there is no evidence presented on record that modifying administration rate of Unger would have been unlikely to produce productive results within the scope of the instant claims.

Examiner adds that Unger explicitly states that any exemplified rate is for purposes of illustration not for purposes of limitation. (see col 45, lines 25-28).

At col 47 Unger explicitly states that

As would be apparent to one skilled in the art, based on the present disclosure, the rate at which the lipid and/or vesicle compositions are preferably administered can vary, depending, for example, on the lipids, polymers, proteins, 15 vesicles, gases and/or gaseous precursors employed, the age and weight of the patient, the mode of administration, the size of the vesicles (in the case of vesicle compositions), and the like. Typically, administration may be carried out at lower rates and the rate can be increased until a desired 20 effect is achieved.

Therefore, Examiner concludes that a person of one ordinary skill, upon reading the teachings of Unger, would have been motivated to increase the rate until a desired effect is achieved. Enhancing the quality of ultrasound images is certainly a well-documented desired effect regardless of the instantly recited intended purpose of "enhancing product homogeneity." Once the rate of Unger is optimized to reach 5-60 minutes, the ultrasound images would have been improved and the instantly intended purpose would have been accomplished. Applicant has not provided any evidence to show the contrary.

9. Finally, the recitation of intended use here, "enhancing product homogeneity" does not impart the instant claims patentable over the cited prior art. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Here, the only difference in the process steps is the duration of administration, which has

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been described by Unger to be an optimizable parameter. Therefore, the instantly recited intended use does not modify the process steps.

10. Applicant also argues that Unger's mode of administration and positioning of the delivery vessel are merely do not suggest methods of enhancing product homogeneity (see Remarks at page 4, 2<sup>nd</sup> para.). In response, Examiner states that since Unger teaches all elemental steps of the instant claims, the intended purpose of the claims are also achieved.

For the reasons of record, the rejection is maintained.

### ***Conclusion***

11. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

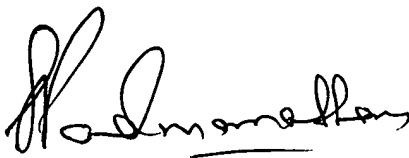
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**